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Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known				
Application Number	10/057,726	_		
Filing Date	January 24, 2002	_		
First Named Inventor	Gary K. OWENS et al.			
Art Unit	1636			
Examiner Name	To Be Assigned	_		
Attorney Docket Number	021258-000200US	7		

U.S. PATENT DOCUMENTS					
		Document Number			
Examiner	Cite No.1	Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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Evaminar	Foreign Patent Document		Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines,		
Examiner Initials*	Cite No.'	Country Code ³	Number ⁴	Kind Code ^s (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶
_ 	1	PCT	WO 94/20629	A1	09-15-1994	Owens, G. K.		
105	2	PCT	WO 99/36101	A1	07-22-1999	Bleadsdale etal		

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²		
B	3	LOFTUS, B. et al. "Genome duplications and other features in 12 Mb of DNA sequence from human chromosome 16p and 16q," <i>Genomics</i> 1999, pp. 295-308, Vol. 60.			

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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				Application Number	10/057,726	OIFE		
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Sheet	11	of	4	Attorney Docket Number	021258-000200US	RADENAS		

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		Document Number				
Examiner	Cite No.	Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
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Examiner Initials*	Cite No. ¹	Country Code ³	Number ⁴	Kind Code ^s (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known **Application Number** 10/057,726 Filing Date January 24, 2002 **First Named Inventor** AU6 Owens, Gary K. 1 6 20 Art Unit Unassigned **Examiner Name** Unassigned RADEMA Attorney Docket Number 021258-000200US

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	Υ	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
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X	AA	AIKAWA et al., "Human smooth Muscle Myosin Heavy Chain Isoforms as Molecular Markers for Vascular Development and Athersclerosis," <u>Circulation Research</u> , 73(6):1000-1012 (1993).	
	AB	AIKAWA et al., "Redifferentiation of Smooth Muscle Cells After Coronary Angioplasty Determined via Myosin Heavy chain Expression," Circulation, 96(1):82-90 (1997).	
	AC	BABIJ et al., "Tissue-specific and developmentally regulated alternative splicing of a visceral isoform of smooth muscle myosin heavy chain," Nuc. Acids Res., 21(6):1467-1471 (1993).	
	AD .	BABJI et al., "Differential expression of SM1 and SM2 myosin isoforms in cultured vascular smooth muscle," Am. J. Physiol., 262:C607-C613 (1991).	
	AE	BABJI et al., "Characterization of a mammalian smooth muscle myosin heavy-chain gene: Complete nucleotide and protein coding sequence and analysis of the 5' end of the gene," PNAS, 88:10676-10680 (1991).	
	ΛF	BABJI et al., "Myosin Heavy Chain Isoform diversity in Smooth Muscle is Produced by Differential RNA Processing," J. Mol. Biol., 210:673-679 (1989).	
	AG	BORRIONE et al., "Myosin heavy-chain isoforms in adult and developing rabbit vascular smooth muscle," <u>Eur.</u> <u>J. Biochem.</u> , 183:413-417 (1989).	
	АН	BOUVAGNET et al., "Multiple Positive and Negative 5' Regulatory elements control the Cell-Type-Specific expression of the Embryonic Skeletal Myosin Heavy-Chain Gene," Molecular and Cellular Biol., 7(12):4377-4389 (1987).	
	ΑI	CHAMLEY-CAMPBELL et al., "What Controls Smooth Muscle Phenotype," Atherosclerosis, 40:347-357 (1981).	
	AJ	FIRULLI et al., "Modular regulation of muscle gene transcription: a mechanism for muscle cell diversity," <u>Trends in Genetics</u> , 13(9):364-369 (1997).	
	AK	FISHER et al., "Developmental and Tissue Distribution of Expression of non Muscle and Smooth Muscle Isoforms of Myosin Light Chain Kinase," <u>Biochem. and Biophys. Res. Comm.</u> , 217(2):696-703 (1995).	
	AL	FRID et al., "Myosin Heavy-Chain Isoform Composition and distribution in Developing and Adult Human Aortic Smooth Muscle," J. Vasc. Res., 30:279-292 (1993).	
	АМ	KALLMEIER et al., "A Novel Smooth Muscle-specific Enhancer Regulates Transcription of the Smooth Muscle Myosin Heavy Chain Gene in Vascular Smooth Muscle Cells," J. Biol. Chem., 270(52):30949-30957 (1995).	
l	AN	KATOH et al., "Identification of Functional Promoter Elements in the Rabbit Smooth Muscle Myosin Heavy Chain Gene," J. Biol. Chem., 269(48):30538-30545 (1994).	
DS	ΛО	KAWAMOTO et al., "Characterization of Myosin Heavy Chains in Cultured Aorta Smooth Muscle Cells," <u>J.</u> <u>Biol. Chem.</u> , 262(15):7282-7288 (1987).	

Examiner Signature	Malle	Date Considered	12/12/03

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	3	of	4
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	Complete if Known
Application Number	10/057,726
Filing Date	January 24, 2002
First Named Inventor	Owens, Gary K.
Art Unit	Unassigned AUS 1 8 2002
Examiner Name	Unassigned
Attorney Docket Number	021258-000200US
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		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2	
S	AP	KELLEY et al., "An Insert of Seven Amino Acids Confers Functional Differences between Smooth Muscle Myosins from the Intestines and Vasculature," J. Biol. Chem., 268(17):12848-12854 (1993).		
	AQ	KOCHER et al., "Cytoskeletal Features of Normal and Atheromatous Human Arterial Smooth Muscle Cells," <u>Human Pathology</u> , 17(9):875-880 (1986).		
	AR	KOCHER et al., "Phenotypic Features of Smooth Muscle Cells during the Evolution of Experimental Carotid Artery Intimal Thickening biochemical and Morphologic Studies," <u>Laboratory Invest.</u> , 65(4):459-470 (1991).		
	AS	HAMADA et al., "Distinct vascular and intestinal smooth muscle myosin heavy chain mRNAs are encoded by a single-copy gene in the chicken," <u>Biochem. Biophys. Res. Comm.</u> 170(1):53-58 (1990).		
	AT	MADSEN et al., "Smooth muscle-Specific Expression of the Smooth Muscle Myosin Heavy Chain Gene in Transgenic Mice Requires 5' -Flanking and First Intronic DNA Sequence," <u>Circulation Research</u> , 82:908-917 (1998).		
	ΑU	MADSEN et al., "Identification of a Positive CIS Element in the Rat Smooth Muscle Myosin Heavy Chain Promoter," Federation of American Societies of Experimental Biology Journal, 10(3):A343, abst. 1977 (1996).		
	AV	MADSEN et al., "Interaction of CArG Elements and a GC-rich Repressor Element in Transcriptional Regulation of the Smooth Muscle Myosin Heavy Chain Gene in Vascular Smooth Muscle Cells," J. Biol. Chem., 272(47):29842-29851 (1997).		
	۸W	MADSEN et al., "Expression of the Smooth Muscle Myosin heavy Chain Gene Is Regulated by a Negative-acting GC-rich Element Located between Two Positive-acting Serum Response Factor-binding Elements," J. Biol. Chem., 272(10):6332-6340 (1997).		
	AX	MANABE et al., "CArG elements control smooth muscle subtype-specific expression of <i>smooth muscle myosin</i> in vivo," J. Clin. Invest., 107(7):823-834 (2001).		
	AY	MANABE et al., "The Smooth Muscle Myosin Heavy Chain Gene Exhibits Smooth Muscle Subtype-selective Modular Regulation in Vivo*," J. Biol. Chem., 276(42):39076-39087 (2001).		
	ΑZ	MIANO et al., "Smooth Muscle Myosin Heavy Chain Exclusively Marks the Smooth Muscle Lineage During Mouse Embryogenesis," Circulation Research, 75:803-812 (1994).		
	ВА	NAGAI et al., "Identification of Two Types of Smooth Muscle Myosin Heavy Chain Isoforms by cDNA Cloning and Immunoblot Analysis*," J. Biol. Chem., 264(17):9734-9737 (1989).		
	ВВ	OWENS, G.K., "Regulation of Differentiation of Vascular Smooth Muscle Cells," Physiological Reviews, 75(3):487-517 (1995).		
	ВС	REGAN et al., "Development of a Smooth Muscle-Targeted Cre Recombinase Mouse Reveals Novel Insights Regarding Smooth Muscle Myosin Heavy Chain Promoter Regulation," Circ. Res., 87:363-369 (2000).		
\$3	BD	REUSCH et al., "Mechanical Strain Increases Smooth Muscle and Decreases Nonmuscle Myosin Expression in Rat Vascular Smooth Muscle Cells," Circulation Research, 79:1046-1053 (1996).		

Examiner Signature	DEUD	Date Considered	12/12/03	

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Sheet

	Complete if Known	
Application Number	10/057,726	7010
Filing Date	January 24, 2002	7
First Named Inventor	Owens, Gary K.	R AUG . C o
Art Unit	Unassigned	# 2005
Examiner Name	Unassigned	The state of the s
Attorney Docket Number	021258-000200US	War and

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
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BE R		ROSS et al., "The pathogenesis of atherosclerosis: a perspective for the 1990s," Nature, 362:801-809 (1993).	
	BF	ROVNER et al., "Two different heavy chains are found in smooth muscle myosin," Am. J. Physiol., 250:C861-C870 (1986).	
	BG	ROVNER et al., "Expression of Smooth Muscle and Nonmuscle Myosin Heavy Chains in Cultured Vascular Smooth Muscle Cells*," J. Biol. Chem., 261(31):14740-14745 (1986).	
	вн	SARTORE et al., "Myosin Isoform Expression in Smooth Muscle Cells during Physiological and Pathological Vascular Remodeling," J. Vasc. Res., 31:61-81 (1994).	***
	. BI	SARTORE et al., "Myosin heavy-chain isoforms in human smooth muscle," Eur. J. Biochem., 179:79-85 (1989).	
	BJ	SARTORELLI et al., "Muscle-Specific Gene Expression, A Comparison of Cardiac and Skeletal Muscle Transcription Strategies," <u>Circulation Research</u> , 72:925-931 (1993).	
	вк	SCHWARTZ et al., "Developmental Mechanisms Underlying Pathology of Arteries," Physiological Reviews, 70(4):1177-1209 (1990)	
	BL	WANG et al., "Expression of Smooth Muscle Myosin Isoforms in Urinary Bladder Smooth Muscle during Hypertrophy and Regression," <u>Laboratory Investigation</u> , 73(2):244-251 (1995).	
	ВМ	WATANABE et al., "Structure and Characterization of the 5' -Flanking Region of the Mouse Smooth Muscle Myosin Heavy Chain (SM 1/2) Gene," <u>Circulation Research</u> , 78:978-989 (1996).	
	BN	WHITE et al., "Identification of Promoter Elements involved in Cell-Specific Regulation of Rat Smooth Muscle Myosin Heavy Chain Gene Transcription*," J. Biol. Chem., 271(25):15008-15017 (1996).	
	во	WIIITE et al., "Identification of a novel smooth muscle myosin heavy chain cDNA: isoform diversity in the S1 head region," Am. J. Physiol., 264:C1252-C1258 (1993).	
B	ВР	WILLS et al., "Tissue-specific expression of an anti-proliferative hybrid transgene from the human smooth muscle α-actin promoter supresses smooth muscle cell proliferation and neointima formation," Gene Therapy, 8:1847-1854 (2001).	
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